NOV - 6 2000

Special 510(k)
Myotronics-Noromed, Inc

510(k) SUMMARY

Model K7 Evaluation System, 510(k) # K003287

Myotronics-Noromed, Inc.
15425 – 53rd Avenue South
Tukwila, WA 98188
Telephone (206) 243-4214
Contact: Mr. Fray Adib, President

October 17,2000

Device: Model K7 Evaluation System consisting of computer-based mandibular (jaw) tracking capability and surface electromyography (EMG)

Legally marketed predicate device: Model K6-I Diagnostic System, K9222456, 04-15-94 & 10-20-97, Myotronics-Noromed, Inc.

Description of the Device: A computer based system capable of (1) non-invasively tracking the mandible in function and/or identifying its position in space relative to the skull and (2) evaluating muscle groups at rest or in function by means of surface electromyography. The mandible is tracked by means of a tiny magnet affixed to the lower incisors and sensors/software which can identify its position in space. Muscle activity is quantified by means of surface electrodes positioned over the muscle groups being studied. Up to eight sites can be monitored simultaneously.

Intended Use: Used primarily by dentists in the scientific, precision evaluation and recording of mandibular function and study of muscles of mastication. Information is used by the doctor in the diagnosis and management of TMJ/MPD disorders, orthodontic patients, denture patients, and reconstruction patients.

Comparison with predicate device: The Model K7 will have exactly the same intended uses and fundamental scientific technology as its predecessor, the Model K6-I. The design change which is the subject of this premarket notification is purely to update the electronic components to state-of-the-art.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2000

Mr. Fray Adib
President
Myotoronics-Noromed, Incorporated
15425 53rd Avenue South
Tukwila, Washington 98188

Re: K003287
Trade Name: Model K-7 Evaluation System
Regulatory Class: II
Product Code: KZM
Dated: October 16, 2000
Received: October 20, 2000

Dear Mr. Adib:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucente for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003287

Device Name: Model K-7 Evaluation System

Indications for Use

For Jaw Tracking functions of this device:

- Tracks mandibular movement and position
- For the diagnosis of functional disorders such as TMJ/MPD syndrome, muscle tension, bruxing, and instability of occlusion
- Identification of mandibular rest position
- Identification of interocclusal distance and freeway space
- Monitors the position of the jaw in three dimensions
- Represents the spatial position of the mandibular incisal edge relative to the skull

For electromyographic function of this device:

- Intended for use for the muscles of mastication, especially temporalis masseter, and digastric
- Designed to perform a limited number of functions in dental diagnosis

(Continued on page 2)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

K003287